UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/820,316 | 04/07/2004 | Syed F.A. Hossainy | 50623.285 | 8511 |

7590 09/24/2007

Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

| EXAMINER | |
|---|---|
| LIN, JAMES | |
| **ART UNIT** | **PAPER NUMBER** |
| 1762 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 09/24/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/820,316 | HOSSAINY ET AL. | |
| | Examiner | Art Unit | |
| | Jimmy Lin | 1762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,5-9,11-12,14,16-31,57-62 and 65-70* is/are pending in the application.

4a) Of the above claim(s) *6,7,11,12,14,17,20,30,58,66 and 68-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,8,9,16,18,19,21-29,31,57,59-62,65 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Newly submitted claim 30 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 30 requires the wall membrane of the balloon to comprise pores formed in a non-porous material while claim 29 requires a distinct species of the wall membrane being made from a porous material. The wall membrane material of claim 29 is inherently porous while the material of claim 30 has pores formed through some sort of process such as laser drilling. Additionally, Applicant states "Claim 29 recites a method that uses a porous balloon material. Claim 30, *directed to a different embodiment*, recites forming pores in a nonporous balloon material" (emphasis added by Examiner) (see pg. 12, lines 1-2 of Applicant's arguments filed 8/24/2007). Such is statement of admittance that the claims are directed to independent and distinct species.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 30 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 21, 24-26, 28-29, 31, 57, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al. (U.S. Publication 2002/0037358).

Barry discloses a method of modifying a balloon catheter, the method comprising:

inflating a nylon balloon of a catheter to an inflated state;

applying paclitaxel/polyurethane mixture in a fluid carrier (paclitaxel is a therapeutic drug);

removing the fluid carrier from the balloon leaving a dry form of the paclitaxel/polyurethane mixture on the surface of the balloon [0075].

Barry teaches that the balloon is in its substantially deflated state prior to insertion into a patient (i.e., deflating a balloon to a collapsed configuration or an under inflated state in preparation for the intended use of the balloon) ([0046]; Fig. 1b).

Barry teaches that the balloon can be made of nylon, but does not explicitly teach that nylon is porous. However, the Applicant exemplifies nylon as a suitable porous material that can be used as the balloon material (see pg. 6, lines 16-18 of the original specification as filed). Thus, the nylon balloon of Barry must necessarily be at least somewhat porous and at least some of the paclitaxel/polyurethane mixture must necessarily be deposited within the pores of the nylon.

Claims 25-26: Paclitaxel is saturated (i.e., dissolved) in the carrier fluid.

Claim 28: Paclitaxel is a drug.

Claim 24: Barry does not explicitly teach maintaining the inflated state at the same or generally the same level during the application of the substance to the balloon. However, Barry provides no teaching or reasoning for modifying the inflated state of the balloon during deposition. One of ordinary skill in the art would have inflated the balloon prior to deposition and would not have been concerned with the inflated state during deposition. Therefore, the inflated state of the balloon would have remained substantially the same during deposition because one of ordinary skill would not have actively modified the inflated state.

Claims 29,57,67: As discussed above, the nylon balloon of Barry must necessarily be porous because the Applicant exemplifies nylon as a suitable porous material.

Barry does not explicitly teach collapsing the pores after applying the substance to the balloon. However, inflating the balloon would have necessarily opened up the pores because the balloon surface stretches during inflation and the pores would have expanded. In a similar manner, subsequently deflating the balloon would have necessarily collapsed the pores.

Claim 31: The balloon is inflated prior to deposition.

***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 21, 24-26, 28-29, 31, 57, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. (U.S. Publication No. 2002/0187288) in view of Barry '358.

Lim discloses a method of making a balloon catheter [0006]. The balloon of the catheter can be made of a porous silicon polyurethane [0022]. Lim teaches that the medical device of the invention can have a therapeutic or diagnostic agent impregnated into the porous silicon polyurethane for delivery within a patient. The device is impregnated with the agent by filling the pores of the silicon polyurethane by dipping, spraying, or other methods [0023]. The silicon polyurethane is the wall member of the balloon, wherein the wall member allows the balloon to inflate and deflate on the catheter assembly.

Lim does not teach the details of the coating method of the agent. Specifically, Lim does not teach inflating the balloon to an inflated state and deflating the balloon. However, Barry teaches that the steps of inflating a balloon of a catheter to an inflated state, applying a therapeutic agent to the inflated state of the balloon (Example 9), and deflating the balloon prior to insertion into a patient ([0046]; Fig. 1b) are well known within the art of impregnating a catheter balloon. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have applied the impregnating steps of Barry to the catheter balloon of Lim with a reasonable expectation of success because Barry teaches that such steps for impregnating a balloon with a therapeutic agent is operable in the art.

Claim 28: The therapeutic agent is a drug.

Claims 24-26, 29, 31, 57, and 67 are rejected for substantially the same reasons as discussed above over Barry.

6. Claims 22-23 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '358, as applied to claim 21 above, in view of Reiss (U.S. Publication No. 2003/0032963).

Claim 23: Barry is discussed above. Barry teaches that the balloon can be inflated prior to deposition, but does not explicitly teach that the inflated state is in a range of an intended

expanded configuration of the balloon. However, Reiss teaches that it is well known to wholly inflate (i.e., an inflated state in a range of an intended expanded configuration) the balloon in preparation for applying a coating to a balloon of a catheter. Because Barry teaches the need to inflate the balloon, it would have been obvious to one of ordinary skill in the art at the time of invention to have wholly inflated the balloon of Barry with a reasonable expectation of success since Reiss teaches that such an inflated state of a catheter balloon is operable for deposition.

Claim 22: Reiss teaches a wholly inflated state of the balloon, but does not explicitly teach that the inflated state is greater than a range of an intended expanded configuration of the balloon and less than a diameter at which the balloon becomes damaged or unsuitable for use. However, an inflated state greater than a range of an intended configuration can be interpreted to be having one extra molecule of fluid more than an inflated state at its intended expanded configuration. A *prima facie* case of obviousness exists where the claimed ranges and prior art do not overlap but are close enough that one in ordinary skill in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 f.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See MPEP 2144.05. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have inflated the balloon to an inflated state greater than a range of an intended expanded configuration as opposed to the wholly inflated state of Reiss with a reasonable expectation of success because the state of inflations are so close that one of ordinary skill in the art would have expected the balloons to have similar properties, especially in the absence of unexpected results. In addition, it would have been obvious to one of ordinary skill in the art at the time of invention to have inflated the balloon so that the balloon does not become damaged or unsuitable for its intended use of insertion into a patient because a consumer would be unlikely to purchase a damaged or unsuitable balloon and because such unsuitability would defeat the intended purpose of the balloon catheter used for insertion into a patient.

Claims 59-61: Barry does not explicitly teach that the balloon can be deflated prior to drying. However, Reiss teaches that deflating the balloon prior to drying is well known in the art [0203]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have deflated the balloon of Reiss prior to drying with a reasonable

expectation of success because Barry teaches the need to deflate the balloon and because Reiss teaches that such order of steps is operable in the art. Additionally, the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. See, for instance, *In re Burhans,* 154 F.2d 690, 69 USPQ 330 (CCPA 1946). One of ordinary skill would have expected similar results when performing the drying step at any time of the balloon modification method. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have deflated the balloon of Barry at anytime, including prior to or during the drying process, because the Applicant has not shown that the order of steps would have unexpected results.

7. Claims 22-23 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim '288 in view of Barry '358, as applied to claim 21 above, and further in view of Reiss '963.

8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '358, as applied to claim 21 above, in view of Reiss (U.S. Patent 6,913,617).

Barry is discussed above, but do not explicitly teach that the therapeutic agent is supersaturated in the carrier fluid.

Reiss teaches that a method of coating an implantable device (i.e., a balloon catheter), wherein a mixture of a therapeutic substance and a carrier fluid can be coated onto the device. The therapeutic substance can be supersaturated in the carrier fluid (col. 9, lines 11-25). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have coated the balloon catheter of Barry with a supersaturated solution of therapeutic agent in a carrier fluid with a reasonable expectation of success because Reiss teaches that coating a supersaturated solution of a therapeutic substance is suitable in the art of implantable medical devices.

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lim '288 in view of Barry '358 as applied to claim 21 above, and further in view of Reiss (U.S. Patent 6,913,617) for substantially the same reasons as discussed immediately above.

10. Claims 1, 5, 8-9, 19, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss et al. (U.S. Publication 2003/0032963).

The rejection is of record in the Office Action filed 5/15/2007.

11. Claims 1, 5, 8-9, 19, 62, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '358 in view of Reiss et al. (U.S. Publication 2003/0032963).

The rejection is of record in the Office Action filed 5/15/2007.

12. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss '963 as applied to claim 1 above, in view of Fukaya '066.

The rejection is of record in the Office Action filed 5/15/2007.

13. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '358 as applied to claim 1 above, in view of Fukaya '066.

The rejection is of record in the Office Action filed 5/15/2007.

***Response to Arguments***

14. Applicant's arguments filed 8/24/2007 have been fully considered but they are not persuasive.

Claims 21, 24-26, 28-29, 31, 57, and 67 as rejected over Barry '358:

Applicant argues on pg. 10-11 that Barry does not teach depositing a substance within a wall membrane that is enclosed at one end of the catheter assembly such that the enclosed wall membrane allows the balloon to inflate and deflate on the catheter assembly. This argument is incorrect because Barry teaches a method of applying a paclitaxel/polyurethane mixture to a nylon balloon. Applicant exemplifies nylon as one of the preferred porous materials used as the

wall membrane (pg. 6, lines 16-18). Thus, the nylon balloon of Barry is necessarily porous and the paclitaxel/polyurethane mixture is applied onto a porous balloon membrane.

Applicant argues on pg. 12 that a dissolved solution does not mean the same thing as a saturated solution. However, Barry teaches that a stock saturated solution of paclitaxel is used [0072]. Because the solution is saturated with the therapeutic agent, the solution must necessarily have the therapeutic agent dissolved in the solvent. In essence, a saturated solution of a compound must necessarily have the compound dissolved in the solution.

Claims 1, 5, 8-9, 19, and 62 as rejected over Reiss '963:

Applicant argues on pg. 13-14 that one of ordinary skill would not have construed hyper-inflated as falling within the range of balloon pressures that produce no noticeable differences from an intended use configuration because the description of these separate states is clearly intended to convey the idea of depositing more or less substance based on the degree of inflation of the balloon. Applicant further argues that the construction adopted in the Official Action takes no account of the teaching for controlling the amount of deposited substance based on the inflated state of the balloon. However, the range of pressures of a hyper-inflated state begins where the range of pressures of an intended-use configuration stops. The transition from one inflated state to the other is the difference of one molecule of fluid. In particular, one extra molecule of fluid added to an intended-use configuration would make the balloon become hyper-inflated. Thus, the maximum pressure of intended-use configuration and the minimum pressure of the hyper-inflated state are so close that one of ordinary skill would not expect any significant difference.

Applicant argues on pg. 15 that one of ordinary skill would have been discouraged from operating a balloon within the hyper-inflated range as this raises an unacceptable risk of causing damage to the balloon. However, it was well known in the art at the time of invention that that balloon of a catheter can safely be expanded to a hyper-inflated state (e.g., see abstract of U.S. Patent No. 6,585,926 to Mirzaee).

***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is 571-272-8902. The examiner can normally be reached on Monday thru Friday 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL

JL

TIMOTHY MEEKS
SUPERVISORY PATENT EXAMINER